FEB 2 0 2001

K003659

510(k) Summary

Bionx Implants Inc.

PLGA Pin

Submitter's Name, Address, Telephone Number, and Contact Person

Bionx Implants, Inc.
1777 Sentry Parkway West
Gwynedd Hall, Suite 400
Bluebell, PA 19422

Contacts: Gerard S. Carlozzi
President and Chief Executive Officer
Phone: (215) 643-5000
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Bionx Implants Ltd.
Tuija Annala
Quality Manager
P.O.Box 3
FIN-33721 Tampere
Finland
Phone: 358-3-316 5679
Facsimile: 358-3-316 5629

Date prepared: November 7th, 2000

Name of the device:

A. Trade or Proprietary Name: PLGA Pin

B	Common Name:	Bioabsorbable bone fixation pin
C.	Classification Name:	Bone Fixation Pin, class II, HTY

Predicate Devices:

The predicate devices are Bionx Implants Inc. Biofix SR-PGA Pin (K890902), SmartPin™ (K925098) and SmartNail™ (K993074). Also our competitors have comparable predicate devices in the market, like Johnson & Johnson Orthopedics, Inc. Orthosorb (K864912, K882979 and K901256) and Synthes (U.S.A) Polypin (K961608).

Intended Use:

PLGA Pin is indicated for fixation of fragments of fractured non-load bearing bones, osteotomies and arthrodeses, for example in the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments in the presence of appropriate immobilization.

Device Description:

The device description of PLGA Pin is as follows.

- Composed of poly-L/G-lactide copolymer
- Lengths 20, 40 and 60mm
- Diameters 1.1, 1.5, 2.0 and 3.2mm

The dimensions and shape are completely identical with the Biofix SR-PGA Pin (K890902) and SmartPin™ (K925098).

Substantial Equivalence:

PLGA Pin has the following similarities to the cleared Bionx Implants Inc. Biofix SR-PGA Pin (K890902), SmartNail (K993074) and SmartPin™ (K925098):

- has the same or similar indicated use
- uses the same operating principle
- incorporates the same basic design
- is manufactured by same machinery
- is packaged and sterilized using the same materials and processes
- has same 2 years shelf life than Biofix SR-PGA Pin (K890902)

PLGA Pins have the following similarities to the cleared Johnson & Johnson Orthopedics, Inc. Orthosorb (K864912, K882979 and K901256) and Synthes (U.S.A) Polypin (K961608):

- has the same or similar indicated use
- use the same operating principle
- incorporate the same basic design

In summary, PLGA Pin described is substantially equivalent to the predicate device. This change of raw material does not raise any problems concerning safety or efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2001

Ms. Tuija Annala
Quality Manager
Bionx Implants, Inc.
c/o Biounx Implants, LTD
P.O. Box 3, Fin-33721
Hermiankatu 6-8 L
Tampere,
Finland

Re: K003659
Trade Name: PLGA Pin
Regulatory Class: II
Product Code: HTY
Dated: November 7, 2000
Received: November 28, 2000

Dear Ms. Annala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K003659

Device Name: PLGA Pin

Indications for Use:

PLGA Pin is intended for use in the fixation of fragments of fractured non-load bearing bones, osteotomies and arthrodeses, for example in the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments.

PLGA Pin is not intended for use in and is contraindicated for: 1) Fractures and osteotomies of cortical bone (except cortical bones of the foot and the hand), 2) Fractures and osteotomies in weight bearing cancellous bone, 3) Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient co-operation cannot be guaranteed (e.g. alcoholism).

(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003659